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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,855	11/29/2001	Jerome Segal	70802.01	6694

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EXAMINER	
AHMED, AAMER S	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,855	SEGAL ET AL.	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *24 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *39* is/are allowed.

6)☒ Claim(s) *31-38 and 45-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendments as to correction of the specification, Page 14, line 19 of the specification have been noted and entered. Furthermore, applicant's amendment of the drawings have been noted and entered. In addition, applicant's correction of claims 31 and 32 have been noted and entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31-32, 34-35, 37-38, 46-47, 53, 61, 64-68, 74, 82 and 85-88 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Brown, III et al (6,219,577). Brown, 111 et al. discloses an iontophoresis, electroporation and combination catheter for local drug delivery to arteries and other body tissues, comprising, a catheter (10) having distal end (14), a proximal end (12), and an iontophoretic transport means (24), the catheter having one lumen (see Figure 3) or more lumens (see Figure 4); a cylindrically shaped expansion member (20) coated or impregnated with a drug or other therapeutic agent positioned on the distal end of the catheter, the cylindrically shaped expansion member having a first contracted diameter (see Figure 1) and

a second expanded diameter (see Figure 2), the second expanded diameter being larger than the first contracted diameter; see Column 8, lines 13-27, Column 9, lines 1-26; Column 10, lines 13-17 and lines 35-68; Column 11, lines 22-63; Column 14, lines 17-68; and Column 15, lines 1-22 and lines 62-63.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577) in view of Gencheff et al. (US 5,423,744). Brown, 111 et al. discloses the invention as claimed with the exception of the method step of positioning a guidewire in the body passageway, and wherein the advancing step is accomplished by threading the expansion member over the guidewire.

Gencheff et al. discloses a catheter system for the deployment of biological material, as shown in Figures 7-10, comprising the method step of positioning a guidewire in the body passageway, and wherein the advancing step is accomplished by threading the expansion member over the guidewire, see Column 10, line 60 through Column 11, line 20. It would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s disclosed method of use with the added steps of positioning a guidewire in the body passageway,

and threading the expansion member over the guidewire, so as to more effectively control placement of the device at the treatment site.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, 111 et al. (US 6,219,577 B1) in view of Dubrul et al. (US 6,450,989 A).

Brown, 111 et al. discloses the invention as claimed with the exception of the cylindrically shaped expansion member comprising a first plurality of flexible elongate elements helically wound in a first direction or rotation and a second plurality of flexible elongate elements helically wound in a second direction of rotation to form a braid.

Dubrul et al. discloses a dilating and support apparatus comprising a dilation mechanism (9), as depicted in Figures 4-A and 4-B, made of an open, mesh metal braid, which allows for perfusion therethrough and is formed by a "Maypole" dance of filament carriers to create a zigzag pattern, wherein one filament moves helically clockwise and the other moves helically counter-clockwise, see Column 13, line 35 through Column 14, line 28; Column 17, lines 30-31; and Column 21, line 4 through Column 22, line 55.

It would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s cylindrically shaped expansion member with an open, mesh braid as taught by Dubrul et al. so as to increase the amount of surface area of the device in contact with the vessel wall thereby enabling more controlled and accurate delivery of medicament to affected wall tissue.

Claims 48, 49, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, 111 et al. (US 6,219,577 B1) in view of Segal (US 5,527,282 A). Brown, 111 et al. discloses the invention as claimed with the exception an anticoagulant, such as heparin or the

like. Segal discloses a vascular dilatation device for localized delivery of heparin, TPA, hirudin or various anti-thrombin agents, see Column 10, lines 55-61. It would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s catheter for local drug delivery with heparin delivery as taught by Segal, so as to prevent clotting of the blood adjacent the dilation device.

Claims 48, 49, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, 111 et al. (US 6,219,577 B1) in view of Tsugita (US 6,142,987 A). Brown, 111 et al. discloses the invention as claimed with the exception an anticoagulant, such as heparin or the like.

Tsugita discloses an endovascular filter device coated with heparin and heparinoids, see Column 5, lines 31-33.

It would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s cylindrically shaped expansion member with a heparin/heparinoid coating as taught by Tsugita, so as to reduce thrombi formation of the flexible elongate elements which comprise the expansion member thus ensuring adequate sustained perfusion therethrough.

Claims 50-52, 54-58, 62, 63, 71-79, 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, 111 et al. (US 6,2 19,577 B 1) in view of Lennox (US 6,280,411 B1), Palasis et al. (US 6,369,039 B1), or Naimark et al. (US 6,638,246 B1).

Brown, 111 et al. discloses the invention as claimed with the exception of Applicant's claimed medicament groups as outlined in Applicant's Claims 50-52, 54-58, 62, 63, 71-79, 83 and 84.

Lennox (Column 4, line 22 through Column 5, line 35), Palasis et al. (Column 4, line 64 through Column 6, line 22), and Naimark et al. (Column 8, line 50 through Column 10, line 23), all individually, discloses a device for localized delivery of drug agents comprising an expansion member (210, 120, 10/20N208/30/40N408/50/60/80A/80B, respectively) coated with a medicament comprising a promoter of vascular cell growth, a transcriptional activator, an inhibitor of vascular cell growth, a growth factor receptor antagonist, a cholesterol-lowering agents, a vasodilating agent, an agent that interferes with endogenous vasoactive mechanisms, estrogen, a smooth muscle inhibitor, a compound that inhibits cellular proliferation, and paclitaxel.

It would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s cylindrically shaped expansion member with a variety of drugs as taught by Lennox, Palasis et al. or Naimark et al., so as to enable treatment of a variety of conditions including localized disease and/or vessel occlusion.

Claims 59, 60, 80 and 81 are rejected tmder 35 U.S.C. 103(a) as being unpatentable over Brown, 111 et al. (US 6,2 19,577 B1) in view of Hanson et al. (US 5,985,307A). Brown, 111 et al. discloses the invention as claimed with the exception of Applicant's claimed medicament groups as outlined in Applicant's Claims 59, 60, 80 and 81.

Hanson et al. (Column 18, line 50 through Column 19, line 339 and Column 26, line 62 through Column 27, line 3) discloses a device for localized delivery of drug agents comprising an expansion member (50) containing a medicament comprising an agent that modulates intracellular calcium binding proteins, and a receptor blocker for contractile agonists.

It would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s cylindrically shaped expansion member with a variety of drugs as taught by Hanson et al., so as to enable treatment of a variety of conditions including localized disease and/of vessel occlusion.

Allowable Subject Matter

Claim 39 is allowed.

Response to Arguments

Applicant's arguments filed 05/24/2004 have been fully considered but they are not persuasive. As to applicant's arguments regarding claims rejected under 35 U.S.C. 102(a) or (e), the distinguishing features recited by applicant are not expressed in the claims, moreover, the prior art reference anticipates the claims as currently written. In addition Brown III et al does disclose Applicant's cylindrically shaped expansion member as element (20).

As to applicant's arguments regarding claim rejections under 25 U.S.C. 103(a), the Brown III et al patent when combined with the prior art disclosed makes the applicant's claims unpatentable. Applicant argues that there is lack of motivation for combining each of the references with Brown III et al. As to claims 33 and 36, it would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s disclosed method of use with the added steps of positioning a guidewire in the body passageway, and threading the expansion member over the guidewire, so as to more effectively control placement of the device at the treatment site.

As to claim 45, it would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s cylindrically shaped expansion member with an open, mesh braid as taught by Dubrul et al. so as to increase the amount of surface area of the device in contact with the vessel wall thereby enabling more controlled and accurate delivery of medicament to affected wall tissue.

As to claims 48, 49, 69 and 70, it would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s catheter for local drug delivery with heparin delivery as taught by Segal, so as to prevent clotting of the blood adjacent the dilation device. In addition, it would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s cylindrically shaped expansion member with a heparin/heparinoid coating as taught by Tsugita, so as to reduce thrombi formation of the flexible elongate elements which comprise the expansion member thus ensuring adequate sustained perfusion therethrough.

As to claims 50-52, 54-58, 62, 63, 71-79, 83 and 84, It would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s cylindrically shaped expansion member with a variety of drugs as taught by Lennox, Palasis et al. or Naimark et al., so as to enable treatment of a variety of conditions including localized disease and/or vessel occlusion.

As to claims 59, 60, 80 and 81, it would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s cylindrically shaped expansion member with a variety of drugs as taught by Hanson et al., so as to enable treatment of a variety of conditions including localized disease and/of vessel occlusion.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Aamer Sajed Ahmed

A.A.

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